EXHIBIT U
Part 1

AMERICAN SOCIETY OF CLINICAL ONCOLOGY ASCO

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July 31, 1991

Gail R. Wilensky, Ph.D.
Administrator
Health Care Financing Administration
Department of Health and Human Services
Attention: BPD-712-P
P.O. Box 26686
Baltimore, Maryland 21207

Dear Dr. Wilensky:

The American Society of Clinical Oncology (ASCO) submits the enclosed comments in response to the proposed regulation implementing the fee schedule for physician services furnished to Medicare beneficiaries. 56 Fed. Reg. 25792 (June 5, 1991). ASCO is the national professional medical organization representing physicians who specialize in the treatment of cancer. A majority of the members of ASCO practice in the subspecialty of medical oncology, which will be significantly affected by the proposed rule.

Approximately half of the cancers diagnosed in this country every year are in persons aged 65 or over, who are thus Medicare beneficiaries. ASCO believes that a number of the elements of the proposal will have a serious unintended effect on the many Medicare beneficiaries treated for cancer.

Following is a summary of the principal points made in our comments:

- ASCO urges HCFA to adopt a conversion factor that does not include any reduction based on assumptions about changes in physician behavior or on the effect of the transition provisions.
- ASCO strongly objects to the proposal to reduce payments for drugs. The present payment methodology should be retained pending further study. If HCFA alters the system immediately, it is essential that all costs be considered in establishing the payment formula to preclude imposing out-of-pocket losses on physicians.
- Separate administration payments should be made for all types of chemotherapy, not just infusion.

- In order to determine the accurate current payment amounts for chemotherapy administration in those carrier areas where supplies are paid separately, the supply payments must be bundled into the chemotherapy administration payments, not allocated across all procedure codes.
- A time factor should not be included in the new descriptors of the visit codes.
- The fee schedule amounts for those services that were not included in the June notice should be made available informally, with documentation, as soon as possible.
- Where "starred" procedures are undertaken as part of a chemotherapy procedure, special documentation to justify the accompanying visit charge should not be required.

ASCO appreciates the opportunity to comment on the proposed rules and to participate in implementation of this important physician payment reform. It is essential that the Health Care Financing Administration (HCFA) carefully assess the impact of the changes which are embodied in the proposal. Neither the cause of physician payment reform nor the welfare of beneficiaries will be served if the matters discussed in our comments are not adequately addressed in the final regulation. We would be happy to provide further information requested by HCFA or to discuss any of our comments in more detail.

Sincerely yours,

Joseph S. Bailes, M.D.
Chairman
Clinical Practice Committee

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Enclosure

AMERICAN SOCIETY OF CLINICAL ONCOLOGY COMMENTS ON THE PROPOSED RULES TO IMPLEMENT THE PHYSICIAN FEE SCHEDULE

These comments are submitted by the American Society of Clinical Oncology (ASCO), the national professional medical organization representing physicians who specialize in the treatment of cancer.

CONVERSION FACTOR

We agree with the rest of organized medicine that the proposed calculation of the conversion factor is unfair and should be revised. HCFA should not reduce the conversion factor based on the unproven assumption that physicians will increase the volume of their services to offset payment reductions. In addition, HCFA should not reduce the conversion factor to account for the supposed effect of the transition provisions. The combined effect of these adjustments is to reduce the conversion factor by 16 percent in the first year and to establish a lower base for future years' updates.

This major unwarranted reduction of Medicare payments will thwart a principal intended purpose of the fee schedule, which is to significantly increase Medicare payments to non-procedural specialties like medical oncology. ASCO urges HCFA to adopt a conversion factor that does not include any reduction based on assumptions about changes in physician behavior or on the effect of the transition provisions.

PAYMENT FOR DRUGS

Under the proposed rules, Medicare payment for drugs would be reduced to 85 percent of average wholesale price (AWP), or even lower in the case of "high volume" or "high cost" drugs where HCFA estimates a lower acquisition cost. ASCO strongly objects to this proposal.

A. Background

1. The HCFA Proposal

The drugs subject to this proposal are largely injectable drugs administered in physician offices. ASCO is the specialty society most concerned with this proposal, since many of the drugs covered by Medicare in this situation are related to the treatment of cancer. Moreover, medical oncologists are especially affected since chemotherapy is their primary treatment modality.

Oncologists and other physicians who administer drugs in their offices purchase the drugs from wholesalers, and in some cases directly from manufacturers, hold the drugs in inventory in their offices, and take the drugs from the inventory as they are needed for their patients. This practice differs, of course, from the procedure for most drugs, where the physician writes a prescription that is filled at a pharmacy from the pharmacy's inventory.

Although drugs covered by Medicare are by statute subject to payment on a reasonable-charge basis, the Medicare Carriers Manual directs carriers to limit payment to an amount based on estimated acquisition cost. The estimated acquisition cost is based on a published listing of

AWP, such as in the Drug Topics Red Book. Most carriers pay AWP, while a few pay AWP plus or minus a percentage factor.

Under the proposal, a uniform payment formula would be established at 85 percent of AWP.[1/] In addition, HCFA could, solely through carrier instructions, identify the estimated acquisition cost of "high volume" or "high cost" drugs, and set Medicare payment at the lower of that amount or 85 percent of AWP.

The proposal is based on the results of surveys by the Office of Inspector General (OIG) of the prices paid by pharmacies for drugs. In a 1984 study, OIG determined the prices paid by a sample of pharmacies in six states for a sample of 36 drugs. It found that the pharmacies paid an average of 15.9 percent less than AWP. In its 1989 study, OIG determined the prices paid by pharmacies for 55 high volume drugs, based largely on the prices of a single national wholesaler, and supplemented by price information obtained from certain Arkansas and Louisiana pharmacies. The 1989 study showed the average price of single-source drugs to be 14.4 percent less than AWP, and the average price of multiple-source drugs to be 18.2 percent less than AWP.

2. The Drug Market

The use of any across-the-board rule designed to cover the costs incurred by physicians in acquiring drugs is made very difficult by the enormous variation in prices paid. Surveys, like that of the OIG, that focus on average price obscure the range of prices actually paid. Although there is little definitive information available, some general statements can be made about the characteristics of the market.

Drug manufacturers sell their products to drug wholesalers, who in turn sell them to physicians, pharmacies, and hospitals. Manufacturers also typically sell their products directly to physicians, although there may be restrictions (for example, minimum quantities) that a physician must satisfy before such a direct sale would be made.

The manufacturer's price for sales to wholesalers is, of course, less than the published AWP. Manufacturers will sometimes sell to physicians at the same price as to wholesalers, but often the price to physicians is higher to account for the higher transaction costs of dealing with smaller amounts of product.

1/ We note an apparent discrepancy between the proposal as discussed in the preamble and the text of the proposed regulation. The preamble refers to the published average wholesale price, whereas the proposed regulation (§ 415.34) refers to the "national average wholesale price of the drug as determined by HCFA." Since the underlying rationale of the proposal is that AWP as published in sources such as the Red Book does not reflect the true price, any reference in the regulation must be to published AWP. Insofar as the regulation text suggests that HCFA could determine true average wholesale price and then pay only 85 percent of that, it plainly is inconsistent with the rationale of the rule.

Wholesalers mark up the prices of the products by varying amounts. Some oncologists find that they must pay the full published AWP for certain drugs. More frequently, the wholesale price to oncologists is somewhere between what the wholesaler paid to the manufacturer and the full AWP. Informal surveys indicate that there is little national consistency in the amount of the mark-up for drugs used by oncologists, but rather that there is substantial variation.

There is also a significant difference between pricing for single-source and for multiple-source drugs, as suggested by the 1989 OIG survey. Manufacturers of single-source drugs seem rarely to offer discounts from their list prices. Accordingly, price variation depends on the amount of mark-up taken by wholesalers. Manufacturers of multiple-source drugs, however, seem to offer discounts more frequently. Thus, price variation for these drugs depends both on the manufacturer's price and on the wholesale mark-up.

A noteworthy fact about pricing practices for drugs is that the same price is not available uniformly to all physicians at all times. It appears, not surprisingly, that physicians in larger practices that are able to order large quantities of drugs are more frequently able to obtain lower prices than are physicians in small practices. Prices also vary greatly through time. Many discounted prices are offered only for limited periods of time or under special circumstances.

Although oncologists who are allowed to purchase directly from a manufacturer would ordinarily pay a lower price to the manufacturer than to a wholesaler, many if not most oncologists find that the additional costs of dealing with multiple manufacturers outweigh the savings available. One major manufacturer of oncology drugs has advised ASCO that about 60 percent of its products used by physicians are distributed through wholesaler channels, rather than sold directly to oncologists, presumably because oncologists wish to avoid the extra costs of purchasing directly from manufacturers. Thus, in light of the significant additional administrative costs incurred in purchasing directly from manufacturers, HCFA should not assume that prices available for purchases from manufacturers should be used in determining appropriate payment levels.

The upshot of these facts is that surveys of a sample of physicians, or of prices paid at a particular time, or of average prices may not accurately reveal the degree of variation in prices paid by individual oncologists. As discussed below, since HCFA's policy is to cover the drug costs incurred by physicians, it is important that the policy cover the drug costs of every physician in all circumstances, not simply the average physician or usual situations.

B. Legal Defects in the Proposed Rule

The proposed rule is inconsistent with both substantive and procedural requirements applicable to payment limitations.

1. Substantive Legal Standard

The proposed payment restrictions are based on HCFA's authority under section 1842(b)(8) of the Social Security Act to deviate from the ordinary reasonable charge methodology. That provision authorizes Medicare, in the case of "particular items or services,"